From: **Marc Salit -- Coronavirus Standards WG** msalit@stanford.edu
Subject: CSWG Mtg Summary 18 Dec 2020: Tests & SOPs
Date: December 18, 2020 at 5:32 PM
To: Marc Salit msalit@stanford.edu

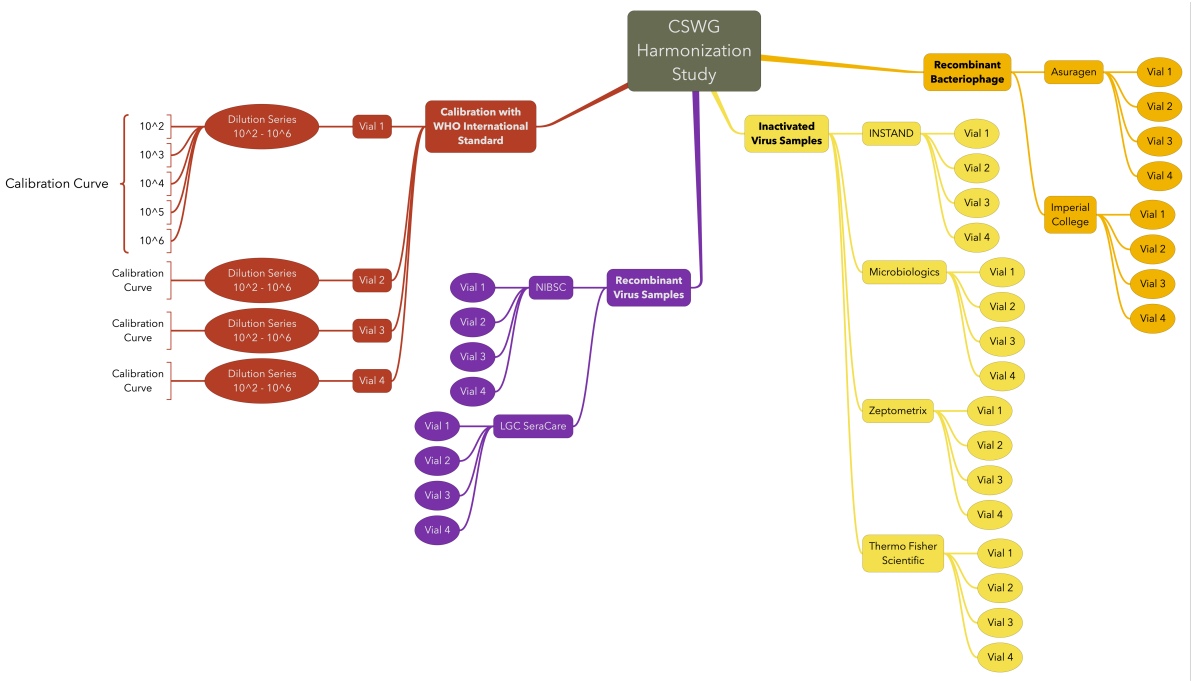
Coronavirus Standards Working Group Meeting Summary: Delving into the Harmonization Study Details II

Dear Colleagues —

Thanks for meeting this morning, Friday 18 December — we did more delving into critical details for our Harmonization Study. At a high level we discussed details of applying the variety of tests in clinical labs to our sample panel, which are not clinical samples, and hence don't have (consistent) human backgrounds; and we introduced the details and principles for a recommended "*Standard Operating Procedure*" to be offered as guidance for the labs.

The slides from this morning's meeting are here, and the link to the meeting recording is here.

Here is a diagram of the experiment as it currently stands (click to download).



We had a brief discussion of nomenclature and agreed to use the definitions in use in ISO documents and the MIQE Guidelines (Cq for quantitation cycle, RT-qPCR for Reverse Transcriptase quantitative PCR).

Sara Suliman presented a plan to specify preparation steps for the samples in the panel, and shared a Google sheet where the protocol is being put together. We were able to fill in some missing data during the meeting -- many thanks Mark and Heinz/Martin/Peter! -- and establish that the materials to be compared against the IS will

fall comfortably in the range of the calibration curve.

- we re-iterated that the recommended SOP will rely on the 4 aliquots of every sample in the panel as the replication design
    - the SOP will NOT call for replicate dilutions from a given vial nor for PCR replication.
- 4 independent calibration curves will be created in each lab from the 4 vials of the WHO International Standard each lab will receive
    - replicate dilutions/calibration curve preparation from each vial will **not** be specified in the recommended SOP
- we will avoid being prescriptive, encouraging labs to use their best practices and...
    - regardless of the protocol followed, the labs will report their process steps in detail in a questionnaire to be provided
- labs will report quantitative results of each measurement, without summarization/statistical analysis, or data reduction, for instance a lab doing RT-qPCR will report Cq for each sample

Some outstanding actions:

- we need to get certification of inactivation for all the inactivated virus samples before shipping
- we need knowledge of what cell lines were used to culture inactivated virus
- Imperial College will consider the protocol range and test volume range when selecting samples to provide.

Here's a link to the Google sheet with the most current information about the samples.

And here's a link to the draft Labs Survey, where we're trying to get information on the tests sufficient to be sure we have a good diversity in the study.

Best regards to all -- the highlight of my 2020 has been getting to know you all and work closely together. I so look forward to our next steps in advancing our mission.

Please stay safe as Winter begins and I wish you all health and wellbeing and good spirits!

Yours,
Marc

Marc Salit, Ph.D.
Director, Joint Initiative for Metrology in Biology — http://jimb.stanford.edu
SLAC National Accelerator Laboratory
Adjunct Professor, Departments of Bioengineering and Pathology
Stanford University